

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Immunosuppressive Drugs Subcommittee of the Antiviral Drugs Advisory
Committee; Notice of Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Immunosuppressive Drugs Subcommittee of the Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 24, 2002, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss new drug applications (NDAs) 21-083/SE1-006 and 21-110/SE1-004, RAPAMUNE (sirolimus) oral solution and tablets, Wyeth-Ayerst Research, approved for prophylaxis of organ rejection in patients receiving renal transplants. As stated in the approved labeling, it is recommended that RAPAMUNE be used in a regimen with cyclosporine

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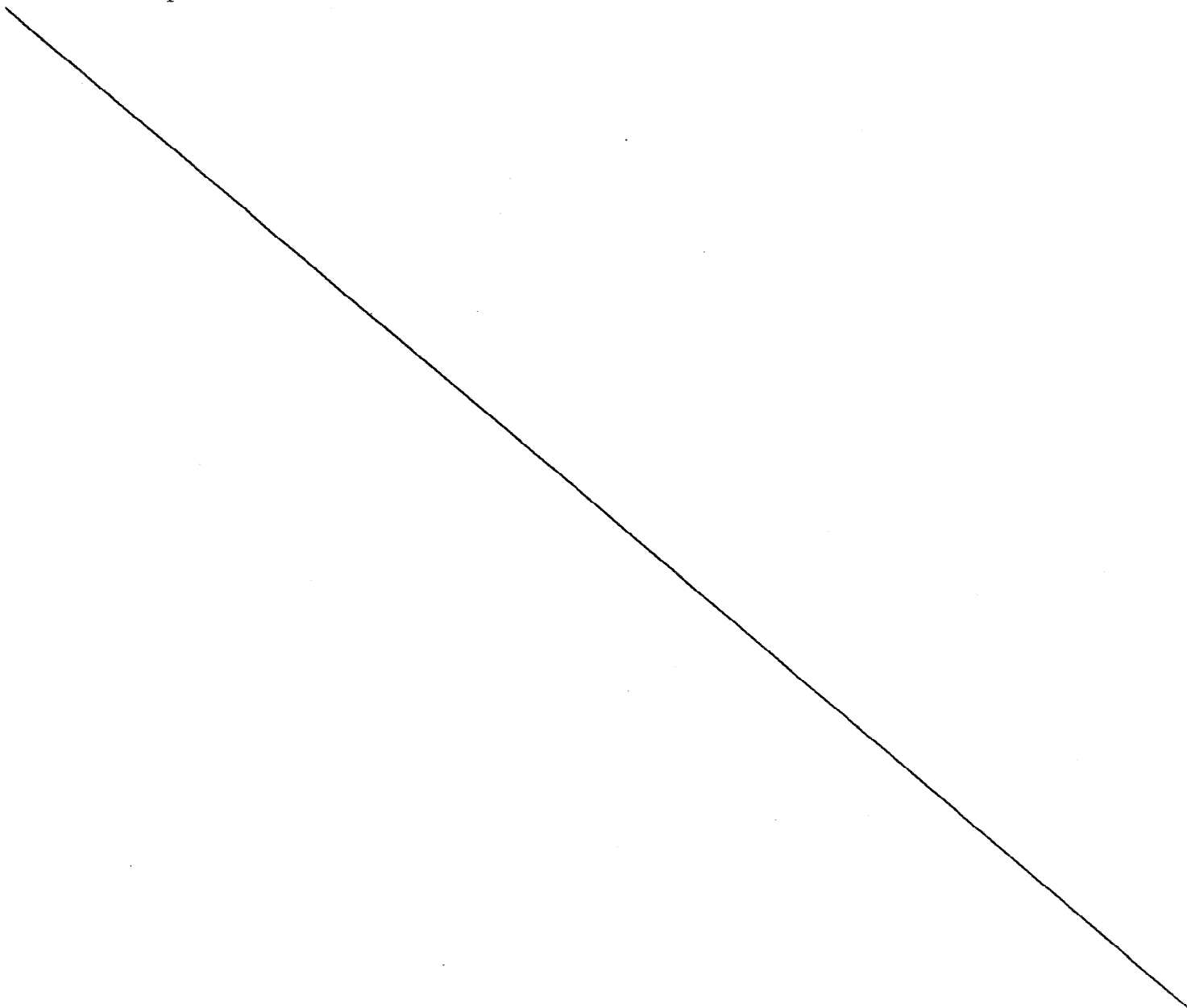
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and corticosteroids. The discussion is for the proposed elimination of cyclosporine from the immunosuppressive regimen 2 to 4 months after transplantation under certain conditions.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by January 16, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 16, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

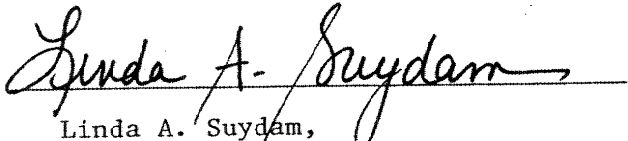


Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 12-19-01

December 19, 2001.


Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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